From: "Zimmerman, Chris" <CZimmerman@amerisourcebergen.com>
Sent: Mon, 6 Feb 2012 14:33:17 -0500 (EST)
To: "Neu, Dave" <DNeu@amerisourcebergen.com>, "Chou, John"<JChou@amerisourcebergen.com>, "Collis, Steven"<SCollis@amerisourcebergen.com>, "Norton, Rita"<RNorton@amerisourcebergen.com>, "Howell, Peyton"<PHowell@amerisourcebergen.com>
Cc: "Mays, Steve" <SMays@amerisourcebergen.com>, "Hazewski, Edward"<EHazewski@amerisourcebergen.com>, "Ross, Paul" <PRoss@amerisourcebergen.com>
Subject: FW: HDMA Talking Points Re: DEA
Attachments: DEA Enforcement Actions -- HDMA Talking Points 020612 (3).doc

---

Dave, I don't believe the talking points address the real issue. We are following the rules that regulate our industry for distributors. DEA has changed their interpretation of those regulations to expand on the distributor's responsibilities for the distribution of controlled substances.

As distributors, we adhere to all regulatory requirements as mandated by the Code of Federal Regulations. The three main regulations for distributors that are relevant to this issue at hand are:

1) **21 CFR 1301.74(a)** - Registrants can only distribute controlled substances to DEA registered locations (pharmacies, hospitals, physicians and distributors);
2) **21 CFR 1301.74(b)** - Distributors must report suspicious orders to DEA; and
3) **21 CFR 1301.71(a)** - Registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.

I feel that most likely all HDMA members meet the requirements above, the issue is that DEA is wanting distributors to go farther than what the regulations stipulate, and potentially in violation of other federal regulations pertaining to HIPAA, and other business practices.

It is the requirement of the professionally trained licensed pharmacist to evaluate the prescription before providing drugs to the patient; and it is the requirement of the professionally trained physician to evaluate the patient before writing a prescription for drugs for the patient.

If there is a deficiency with how a doctor evaluates the patient which leads to diversion, then DEA should take prompt action against the physician's DEA registration. If there is a deficiency with how a pharmacist evaluates the prescription and the patient picking up the prescription that leads to diversion, then DEA should take prompt action against that pharmacist's license and the pharmacy's DEA registration.

I believe the intent of the suspicious order reporting requirement for distributors was to help alert DEA to potential pharmacies and physicians who may not be complying with their requirements. This has now morphed into DEA wanting distributors to not only evaluate the patients that are picking up prescriptions from the pharmacy, but also to evaluate the medical doctors that are writing the prescriptions.

My two cents.

Chris

From: Neu, Dave
Sent: Monday, February 06, 2012 12:58 PM
To: Chou, John; Collis, Steven; Norton, Rita; Howell, Peyton; Zimmerman, Chris
Subject: Fw: HDMA Talking Points Re: DEA

Let's discuss. Double edged sword to say the least.

David Neu
President
AmerisourceBergen Drug Corporation
1300 Morris Drive
Chesterbrook, PA 19087
(610) 727-7206

From: Gray, John [mailto:jgray@hdmanet.org]
Sent: Monday, February 06, 2012 12:45 PM
To: Couch, Ken <kcouch@smithdrug.com>; Dale Smith <dsmith@hdsmith.com>; Neu, Dave; Gray, John <jgray@hdmanet.org>; Julian, Paul <paul.julian@mckesson.com>; Kaufmann, Mike <mike.kaufmann@cardinalhealth.com>; Moody, David <dmoody@mutualdrug.com>; Scherr, Ted <tscherr@dakdrug.com>
Subject: HDMA Talking Points Re: DEA

Gentlemen:

As you know, Cardinal Health has been dealing with the DEA with respect to their distribution facility in Lakeland, Florida. The DEA has scheduled a 3:00 pm (EST) press conference today in Orlando, Florida to discuss this situation. Given the likelihood that HDMA will receive press/media inquiries about this case, HDMA has prepared the attached talking points concerning the larger suspicious order monitoring issue we have been grappling with over the past five years. In the past several years, HDMA has reached out to DEA in attempts to improve cooperation between the Agency and our distributor members regarding this monitoring process. As recently as December 2011, HDMA met with DEA in person to no avail. HDMA has been conservative in our approach to dealing with the DEA in hopes we could develop a more constructive relationship. However, the DEA actions over the past week in Florida suggest that they intend to still pursue distributors in their efforts to curb suspicious orders of controlled substances.

HDMA would like guidance from the Executive Committee regarding the proposed talking points and whether or not the Association should adopt a more open and aggressive posture with respect to our dealings with DEA. The final five (5) talking points represent a much more provocative and forceful perspective for HDMA to share with the general media and press. On the positive side, statements like these will clarify distributor concerns and frustrations in dealing with the DEA. On the negative side, HDMA may undo whatever positive relationship we have worked on with the DEA since 2007.

I appreciate your input and look forward to your response.

John Gray